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09/653,812	09/01/2000	Haig H. Kazazian JR.	53893-5006-02	6101

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DRINKER BIDDLE & REATH
ATTN: INTELLECTUAL PROPERTY GROUP
ONE LOGAN SQUARE
18TH AND CHERRY STREETS
PHILADELPHIA, PA 19103-6996

EXAMINER

FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

MAIL DATE	DELIVERY MODE
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02/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

The amendment filed November 5, 2007 (hereinafter referred to as “the response”) has been entered. Claims 34 and 36-43 have been amended.

Accordingly, Claims 34, 36-44, 46, 47, and 49 remain pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 5, 2007 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34, 36-44, 46, 47, and 49 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced in the Office Actions of 12/17/01, 9/22/04, 6/2/05, 9/21/06, 10/9/07, and the Advisory Action of 12/27/05, and for the reasons discussed herein, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The claims are directed to a transgenic mouse comprising a specific retrotransposon, as well as a sperm cell obtained from a male transgenic mouse comprising said specific retrotransposon. The claims cover transgenic mice having any gene inserted as well as those having any gene disrupted.

Although the claims have been amended to recite a high frequency, insertional mutagenesis model, the specification fails to disclose a transgenic mouse as claimed that has utility as a model of high frequency, insertional mutagenesis. The specification does not describe or enable a high frequency, insertional mutagenesis model mouse comprising the retrotransposon recited in the claims, nor does it describe how such a mouse would be used. As noted at page 5, paragraph 3 of the Office Action of 9/22/04, since the specification does not disclose a transgenic mouse having a useful phenotype as a result of the randomly induced mutations, the skilled artisan would not know how to use the claimed transgenic mouse.

At pages 5-6 of the response, Applicants assert that the transgenic mice are generated so that sperm can be obtained therefrom, wherein the sperm are then used to generate high frequency mutations. Applicants cite Ostertag et al. (2002) for disclosing a transgenic mouse made according to the methods described in the present specification having this use. Applicants further assert that the high frequency, insertional mutagenesis model allows for assessing the mutagenic potential of an animal by assessing the frequency of retrotransposition in the cells of the animal. Applicants point to the specification at page 27, lines 22-29 to page 28, line 1, and assert that the specification discloses that the use for the mouse is to generate mutations in a cell. On the contrary, the specification makes it clear that it is the DNAc molecule that is used to generate high frequency mutations, not the transgenic mouse. The cited paragraph only describes how to make transgenic mice of the invention. There is nothing in the cited paragraph that refers to a use for the claimed transgenic mice. These arguments have already been addressed in the Office Action of June 2, 2005 (see pages 3-5) and again in the Office Action of October 9, 2007. In fact, the transgenic mouse described in the specification (page 27, line 22 to page 28, line 3)

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would have many mutations within a single mouse, including the initial germline genetic modification, followed by many somatic cell modifications, so that the resulting mouse would be a mosaic animal having different mutations in different cells and tissues. Nowhere does the specification teach how to use such a mouse for any particular purpose. The cited reference of Ostertag et al. (2002) explicitly states that transgenic mice provide an *in vivo* model of retrotransposition in mammals and are an important step in the development of a new random mutagenesis system. Such a use does not constitute a specific and substantial utility within the meaning of 35 U.S.C. 101. Likewise, the instant specification only contemplates using the mouse as an object of study, i.e. studying the mouse itself to further elucidate the *in vivo* function of the retrotransposon and to identify random insertional mutations within the genome of the mouse. However, using the claimed invention as an object of study or further research does not constitute a patentable utility within the meaning of 35 U.S.C. 101 because studies such as these do not provide a real world context of use. See MPEP § 2107.01 which explains that “[b]asic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved” is an example of “situations that require or constitute carrying out further research to identify or reasonably confirm a ‘real world’ context of use and , therefore, do not define ‘substantial utilities’.”

Thus, the rejection under 35 U.S.C. 112, first paragraph is maintained, for reasons of record.

Conclusion

No claims are allowable.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a

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request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

/Anne-Marie Falk/

Primary Examiner, Art Unit 1632